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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,506	11/22/2000	Thomas R. Cech	015389-002616US	5211

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/721,506	<b>Applicant(s)</b> CECH ET AL.	
	<b>Examiner</b> Bradley L. Sisson	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 75-78, 80, 83-86, 88, 91-94, 96 and 101-104 is/are pending in the application.
- 4a) Of the above claim(s) 80, 88 and 96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75-78, 83-86, 91-94 and 101-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 73, 80, 81, 88, 89, and 96 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06 November 2003.

### *Claim Rejections - 35 USC § 112*

2. Claims 75-78, 83-86, 91-94, and 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) (“the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed”). Thus, an applicant complies with the written-description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572.

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3. Claims 75, 83, and 91, the three independent claims under consideration, have been amended so to recite added limitations as to the percent identity and the length over which it is to be determined. A review of the specification fails to find support for this limitation and a review of the disclosure also fails to identify where attention has been directed to any supporting passage. Accordingly, the limitations added to claims 75, 83, and 91 constitute new mater.

4. For the above reasons and in the absence of convincing evidence to the contrary, claims 83-86, 91-94, and 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

5. At pages 5-6 of the response received 21 October 2005, hereinafter the response, applicant's representative asserts that the recited claim limitations are fully supported by the original disclosure and that no new mater has been introduced. In support of this position said representative directs attention to columns 139-140 of US Patent 6,166,178 as providing "additional guidance as to how to compare nucleic acid and protein sequences." Additional argument is presented that claims 101-104 are properly dependent upon claim 75.

6. The above arguments have been fully considered and have not been found persuasive towards the withdrawal of the rejection. For convenience, claim 101 is reproduced below.

**101. (Previously presented) The polynucleotide of claim 75, wherein said TRT protein contains a sequence that is at least 95% identical to 100 contiguous amino acids in SEQ. ID NO:2.**

As seen therein, the region of comparison need be but 100 amino acids in length, and that there must be at least 95% identity between said given 100 contiguous amino acids in SEQ ID NO. 2 and that encompassed by the claims. The number of embodiments encompassed by any given 100

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amino acid region are  $4.39 \times 10^{14}$ . The specification does not present an adequate written description of the embodiments encompassed by any one 100mer region, much less an adequate written description for all possible 100mers encompassed by the claim. Furthermore, the specification does not provide an adequate written description of which of the  $4.39 \times 10^{14}$  embodiments found in any given 100mer of SEQ ID NO: 2 actually possess the requisite activity. Absent such detailed description and guidance, the specification does not reasonably suggest that applicant was in possession of the broad genus of embodiments encompassed by the claims.

7. In support of this position attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

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We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise. (Emphasis added)

In accordance with the decision in *In re Shokal*, the need or “a considerably larger number of reductions to practice” is warranted when the genus comprises “hundreds of species.” As seen

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above, just one of the over 1000 possible 100mers taken from SEQ ID NO: 2 would encompass  $4.39 \times 10^{14}$  embodiments when one takes into consideration the number of deletions, additions, and substitutions encompassed. Clearly, the presence of a single species does not provide an adequate written description of the genus of compounds claimed. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

8. For the above reasons, and in the absence of convincing evidence to the contrary, claims 75-78, 83-86, 91-94, and 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

10. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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11. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 75-78, 83-86, 91-94, and 101-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,337,200. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 75, 83 and 91 of the instant application fairly encompass the nucleic acid of claims 1-6 of the '200 patent.

13. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 24-28, 30, 34, and 35 of copending Application No. 09/438,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to isolated nucleic acid that encodes hTRT.

14. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/054,295. Although the conflicting claims are not identical, they

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are not patentably distinct from each other because both sets of claims fairly encompass nucleic acid that encodes hTRT.

16. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-26, 69, 70, 81, and 82 are of copending Application No. 09/721,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to polynucleotide/nucleic acid that encodes hTRT.

18. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 19, and 21-23 of copending Application No. 10/044,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an isolated nucleic acid. While the claimed composition of claim 1 in the '692 application is defined as being "an immunogenic composition," it need only comprise the nucleic acid.

Accordingly, claims drawn to a nucleic acid or to a composition that comprises same, when only are obvious one over the other.

20. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



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21. Claims 75-78, 83-86, 91-94, and 101-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-14, and 23-25 of copending Application No. 10/877,124. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims fairly encompass isolated nucleic acid that encodes hTRT.

22. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to argument

23. At page 7, bridging to page 8 of the response argument is presented that the Office's policy as to requiring an applicant to file a terminal disclaimer should be changed. This argument or request has been fully considered and has not been found persuasive towards the withdrawal of the rejection as there has been no convincing showing of fact that the claims currently before the Office in the instant application do not encompass the embodiments claimed in the '200 patent. To the contrary, applicant's representative asserts that the claims of the '200 patent are drawn to a subset of that now claimed.

24. At page 8, penultimate paragraph, applicant's representative states that a terminal disclaimer is being submitted under separate cover. However, a review of the record fails to find where any terminal disclaimer has been received. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.

25. While said representative asserts at page 8 of the response that the instant application will issue before that of applications 09/721,477, 10/044692, and 10/877124, and that no terminal disclaimer is needed, the provisional rejection is being maintained until such time that the instant

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application does issue first, terminal disclaimer are filed, the claims no longer conflict, or the application goes abandoned.

*Conclusion*

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

27. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
08 January 2006